Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (original) At least one computer readable medium collectively carrying a machine readable database identifying:

first patient eligibility criteria for a first clinical trial protocol; and

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow tasks.

2. (original) A medium according to claim 1, wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol.

3. (original) A medium according to claim 1, wherein said database identifies a term by reference to a controlled medical terminology database.

4. (currently amended) A ~~method~~ medium according to claim 1, wherein said first plurality of workflow tasks includes data management tasks.

5. (currently amended) A ~~method~~ medium according to claim 4, wherein said post-enrollment workflow tasks include post-enrollment patient management tasks.

6. (currently amended) A ~~method~~ medium according to claim 4, wherein said data management tasks include an instruction for a clinician to complete a specified form.

7. (currently amended) A ~~method~~ medium according to claim 4, wherein said data management tasks include an instruction for a clinician to obtain informed consent of a patient.

8. (currently amended) A ~~method~~ medium according to claim 7, wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before said instruction to obtain informed consent.

9. (currently amended) A ~~method~~ medium according to claim 8, wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

10. (currently amended) A ~~method~~ medium according to claim 7, wherein said data management tasks further include an instruction to enroll a patient into a clinical trial.

11. (currently amended) A ~~method~~ medium according to claim 1, wherein said data management tasks include an instruction to enroll a patient into a clinical trial.

12-30 (withdrawn)

31. (currently amended) At least one computer readable medium collectively carrying a library identifying a plurality of machine readable protocol databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks.

32. (original) A medium according to claim 31, further comprising means for providing access to individual ones of said protocol databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

33. (original) A medium according to claim 31, wherein different ones of said protocol databases were prepared by different protocol designers.

34. (original) A medium according to claim 31, wherein each of said protocol databases identifies:

patient eligibility criteria for the respective clinical trial protocol; and

a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks.

35. (original) A medium according to claim 34, wherein each of said protocol databases further identifies preliminary patient eligibility criteria applicable to the respective clinical trial protocol.

36. (original) A medium according to claim 31, wherein each of said protocol databases identifies:

a plurality of patient management tasks for the respective clinical trial protocol; and

a plurality of data management tasks for the respective clinical trial protocol.

37. (original) A medium according to claim 31, wherein at least one of said protocol databases identifies a term by reference to a controlled medical terminology database.

38. (original) A medium according to claim 37, wherein each of said protocol databases identifies a term by reference to a controlled medical terminology database.

39. (original) A medium according to claim 37, wherein each of a plurality of said protocol databases identifies a term by reference to a common controlled medical terminology database.

40. (original) A medium according to claim 31, wherein different ones of said clinical trial protocols address different disease categories.

41. (original) A medium according to claim 31, wherein each of said machine readable protocol databases includes software objects instantiated from a corresponding predefined set of object classes.

42. (original) A medium according to claim 41, wherein all of said machine readable protocol databases include software objects instantiated from a common predefined set of object classes.

43. (original) A medium according to claim 41, wherein a first one of said machine readable protocol databases includes software objects instantiated from a first predefined set of object classes, and a second one of said machine readable protocol databases includes software objects instantiated from a second predefined set of object classes different from said first predefined set of object classes.

44. (original) A medium according to claim 41, wherein the machine readable protocol databases are for clinical trial protocols in a plurality of disease categories,

and wherein the software objects included in each given one of said machine readable protocol databases are instantiated from a set of object classes which corresponds to and is specific to the disease category of the clinical trial protocol of the given protocol database.

45-109. (withdrawn)

110. (currently amended) A clinical trials method, comprising the steps of:

storing in a library of clinical trial sub-protocol components, a first clinical trial sub-protocol component identifying at least one member of the group consisting of a patient eligibility criterion and a patient management protocol workflow task; and

assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library.

111. (currently amended) A method according to claim 110, comprising the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks,

wherein said step of storing a plurality of databases includes said step of storing a first clinical trial sub-protocol component.

112. (original) A method according to claim 111, further comprising the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

113. (currently amended) A method according to claim 110, wherein said step of assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library comprises the steps of:

providing read/write access to said first clinical trial sub-protocol component by a first user; and

providing read but not write access to said ~~said~~ first clinical trial sub-protocol component by a second user.

114. (original) A method according to claim 110, wherein said first clinical trial sub-protocol component includes first and second sub-protocol sub-components.

115. (original) A method according to claim 114, further comprising the steps of:

assigning a first sub-protocol sub-component level user access control to said first sub-protocol sub-component; and

assigning a second sub-protocol sub-component level user access control to said second clinical trials sub-protocol sub-component in said library.

116. (original) A method according to claim 110, further comprising the steps of:

storing in said library a second clinical trial sub-protocol component identifying at least one member of the group consisting of a patient eligibility criterion and a protocol workflow task; and

assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library.

117. (original) A method according to claim 116, wherein said first and second clinical trial sub-protocol components are both components of a common clinical trial protocol.

118. (original) A method according to claim 116, wherein said first and second clinical trial sub-protocol components are components of different clinical trial protocols.

119. (currently amended) A method according to claim 116, wherein said step of assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library comprises the step of providing read/write access to said first clinical trial sub-protocol component by a first user,

and wherein said step of assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library comprises the step of providing read but not write access to said ~~said~~ second clinical trial sub-protocol component by said first user.

120. (currently amended) A clinical trials method, comprising the steps of:

storing a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of a patient eligibility criterion and a patient management protocol workflow task; and

providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users in accordance with predetermined sub-protocol component level access controls.

121. (currently amended) A method according to claim 120, comprising the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks,

wherein said step of storing a plurality of databases includes said step of storing a plurality of clinical trial sub-protocol components.

122. (original) A method according to claim 121, further comprising the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

123. (original) A method according to claim 120, wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users comprises the steps of:

providing read/write access to a first one of said clinical trial sub-protocol components by a first one of said users; and

providing read but not write access to said first clinical trial sub-protocol component by a second one of said users.

124. (original) A method according to claim 123, wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users further comprises the steps of:

providing read/write access to a second one of said clinical trial sub-protocol components by said second user.

125. (original) A method according to claim 120, wherein a first one of said sub-protocol components includes first and second sub-protocol sub-components.

126. (original) A method according to claim 125, further comprising the step of providing access to said clinical trials sub-protocol sub-components by each of a plurality of users in accordance with predetermined sub-protocol sub-component level access controls.

127. (original) A method according to claim 120, further comprising the step of receiving said sub-protocol components from a plurality of different protocol designers.

128. (currently amended) At least one computer readable medium collectively carrying a library identifying a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks, said library further identifying sub-protocol component level user access controls for at least a subset of said sub-protocol components.

129. (currently amended) A medium according to claim 128, wherein said library further identifies a plurality of protocol databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks,

wherein one of said clinical trial sub-protocol components is a component of one of said clinical trial protocols.

130. (original) A medium according to claim 129, wherein said library further identifies protocol-level access controls which control access to individual ones of said databases by each of a plurality of clinical sites.

131. (original) A medium according to claim 128, wherein said sub-protocol component level user access controls include a first control which provides read/write access to a first one of said clinical trial sub-protocol components by a first user and which further provides read but not write access to said first clinical trial sub-protocol component by a second user.

132. (original) A medium according to claim 131, wherein said sub-protocol component level user access controls further include a third control which provides read/write access to a second one of said clinical trial sub-protocol components by said second user.

133. (original) A medium according to claim 128, wherein a first one of said sub-protocol components includes first and second sub-protocol sub-components.

134. (original) A medium according to claim 133, wherein said sub-protocol component level user access controls further include sub-protocol sub-component level user access controls.

135. (original) A medium according to claim 128, wherein first and second ones of said sub-protocol components were prepared by different protocol designers.

136. (currently amended) A ~~method~~ medium according to claim 128, wherein first and second ones of said sub-protocol components are both components of a common clinical trial protocol.

137. (currently amended) A ~~method~~ medium according to claim 128, wherein first and second ones of said sub-protocol components are components of first and second different clinical trial protocols.

A1

138. (original) A medium according to claim 137, wherein said first and second clinical trial protocols address different disease categories.

139. (new) A medium according to claim 1, wherein said post-enrollment workflow tasks include patient management tasks.

A2